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To

Mail Stop Petitions

571-272-0955

*5*71-273**-**8300

Commissioner for Patents

From

W. Jackson Matney, Jr.

202-452-7000

202-452-7074

Client/Matter No.

95176562-005004

Re

Applicant: Lloyd Wolfinbarger, Jr.

Serial No.: 09/940,545 Filed: August 29, 2001

Title: Plasticized Bone and Soft Tissue Grafts and Methods of Making and Using Same

Pages (w/cover)

19

Please see attached Petition to Withdraw Holding of Abandonment for filing with the United States Patent and Trademark office today.

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DOCKET NUMBER: 95:176562-005004 (64230-00005USD2)
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Lloyd Wolfinbarger, Jr.

Serial No.: 09/940,545

Filed: August 29, 2001

For: Plasticized Bone and Soft Tissue Grafts and

Methods of Making and Using Same

Group Art Unit.: 3732

Examiner: David Comstock

Mail Stop Petitions

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir.

CERTIFICATE OF FACSIMILE 37 CFR 1.8

I hereby certify that this correspondence is being transmitted to the United States Patent and Trademark Office via facsimile to (571) 273-8300 on May 4, 2006...

Karen L. F

Signature

PETITION TO WITHDRAW HOLDING OF ABANDONMENT

Applicant asks for withdrawal of a holding of abandonment of Application Serial No. 09/940,545 because a Notice of Appeal was timely filed while the application was pending. The records at the United States Patent & Trademark Office ("USPTO") confirm the following:

- 1. On March 15, 2005, the USPTO mailed an Office Action to Applicant. See Exhibit A, which is attached.
 - 2. September 15, 2005, was the last date to file a response.
- 3. On September 14, 2005, in response to the March 15th Office Action, Applicant submitted a Notice of Appeal to the USPTO and requested a three-month extension of time. *See* Exhibit B, which is attached.
 - 4. This submission occurred before the September 15th deadline.
- 5. On September 21, 2005, the USPTO mailed a Notice of Abandonment stating that a timely reply to an Office Action mailed March 15, 2005 had not been received. See Exhibit C, which is attached. This Notice is clearly in error.
 - 6. The PAIR system still incorrectly indicates that this application has been abandoned.

DOCKET NUMBER: 95176562-005004 (64230-00005USD2) PATENT

7. Applicant's representatives have contacted the Examiner and his Supervisory Primary Examiner to have the application reinstated. Neither would do so.

Because a Notice of Appeal was timely filed on September 14, 2005, before the deadline, Applicant respectfully petitions that the holding of abandonment be withdrawn.

If there are any questions regarding this petition or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

Respectfully submitted,

Stephanie A. Wardwell
Stephanie A. Wardwell

Reg. No. 48,025

Date: May _______, 2006
Baker & McKenzie LLP
815 Connecticut Avenue, NW
Washington, DC 20006
(202) 452-7000
(202) 452-7074 (fax)

EXHIBIT A



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERC United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS	E
P.O. Box 1450	
Alexandria, Virginia 22312-1450	

APPLICATION NO. 09/940,545	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. CONFIRMATION I	
	08/29/2001	Lloyd Wolfinburger JR.	58772.000004 5273	
75	90 03/15/2005		EXAMINER COMSTOCK, DAVID C ART UNIT PAPER NUMBER	
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1445 ROSS AV DALLAS, TX	ENUE, SUITE 3200 75202			
27121210, 111			3732	
			DATE MAILED: 03/15/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
•	09/940,545	WOLFINBARGER ET AL.
Office Action Summary	Examiner	Art Unit
	David Comstock	3732
- The MAILING DATE of this communication app	ears on the cover sheet with the	correspondence address -
Period for Reply	·	
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.12 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period - Fallure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. Soo 37 CFR 1.704(b).	38(a). In no event, however, may a reply be y within the assitutory minimum of thirty (30) d will apply and will expire SIX (6) MONTHS for cause the application to become ABANDO!	timely filed lays will be considered timely. on the mailing date of this communication. NED (35 U.S.C. § 133).
Status	1	
1) Responsive to communication(s) filed on 15 N	ovember 2004 and 07 January	<u>2005</u> .
·	action is non-final.	
3) Since this application is in condition for allowa	nce except for formal matters, p	prosecution as to the merits is
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11,	453 O.G. 213.
Disposition of Claims	•	
4)⊠ Claim(s) 33 and 34 is/are pending in the applic	ation.	
4a) Of the above claim(s) is/are withdraw	wn from consideration.	·
5) Claim(s) is/are allowed.		
6) Claim(s) 33 and 34 is/are rejected.		
7) Claim(s) Is/are objected to.		:
8) Claim(s) are subject to restriction and/o	r election requirement.	
Application Papers		·
9)☐ The specification is objected to by the Examine	r.	
10)☐ The drawing(s) filed on is/are: a)☐ acc	epted or b) objected to by the	e Examiner.
Applicant may not request that any objection to the	- · · · · · · · · · · · · · · · · · · ·	
Replacement drawing sheet(s) including the correct		
11) The oath or declaration is objected to by the Ex	caminer. Note the attached Offic	ce Action or form PTO-152.
Priority under 35 U.S.C. § 119		
12)☐ Acknowledgment is made of a claim for foreign a)☐ All b)☐ Some * c)☐ None of:	priority under 35 U.S.C. § 119	(a)-(d) or (f).
1. ☐ Certified copies of the priority document	s have been received.	
2. Certified copies of the priority document		ation No
3. Copies of the certified copies of the prior	rity documents have been rece	ived in this National Stage
application from the International Bureau		
* See the attached detailed Office action for a list	of the certified copies not recei	ved.
	:	
Attachment(s)	•	
1) Notice of References Cited (PTO-892)	4) 🔲 Interview Summa	rry (PTO-413)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail	Date
 Information Disolosure Statement(s) (PTQ-1449 or PTO/SB/08) Paper No(s)/Mail Date 18 FEB 05. 	5) ☐ Notice of Informa 6) ☐ Other	Patent Application (PTO-152)
8. Patent and Trademark Office	· <u>·</u>	

Page 2

Application/Control Number: 09/940,545
 Art Unit: 3732

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 34 is rejected under 35 U.S.C. 102(e) as being anticipated by Boyce et al. (5,899,939).

Boyce et al. disclose a monolithic bone implant, i.e. whole bone or a portion of whole bone, 20 that is contacted with a liquid organic agent, i.e. a type of polyethylene glycol, and freeze-dried, i.e. lyophilized (see col. 1, lines 6-17; col. 2, lines 9-15; col. 4, lines 20-24 and 45-46; col. 4, line 53-65; col. 5, lines 21-29; and col. 6, lines 8-13, 45-46 and 51-52. It is noted that providing layers and demineralizing the implant are both optional; therefore, the scope of the disclosure includes mineralized bone that is not provided with the layers (id.).

Application/Control Number: 09/940,545

Art Unit: 3732

Page 3

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce et al. (5,899,939) in view of Morse (5,333,626).

Boyce et al. disclose the claimed invention except for explicitly disclosing packaging of the implant. Morse discloses a similar invention that is packaged to preserve sterility and biologic potential in the implant and to avoid contamination and infection in the patient (see Fig. 1 and col. 1, lines 6-18; col. 2, lines 21-26; col. 3, lines 10-12, 21, 31-50, 57-61; col. 4, tines 8-12; col. 5, lines 57-65; col. 6, lines 5-25 and 43-46; and col. 7, lines 40-47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the bone implant as disclosed by Boyce et al. with packaging, in view of Morse, in order to preserve sterility and biologic potential of the bone implant and to avoid contamination and infection in the patient. It would have been further obvious to provide the liquid organic agent in any of numerous ranges of amounts, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

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Response to Arguments

Applicant's arguments filed 15 November 2004 and 07 January 2005 regarding Livesey et al. have been fully considered and are persuasive. Accordingly, the rejections relying on this reference have been withdrawn.

However, Applicant's arguments pertaining to Boyce are not persuasive.

In response to Applicant's argument that Boyce does not anticipate Applicant's invention, it is noted that all of the disclosures in a reference must be evaluated for what they fairly teach one of ordinary skill in the art. *In re Smith*, 32 CCPA 959, 148 F.2d 351, 65 USPQ 167; *In re Nehrenberg*, 47 CCPA 1159, 280 F.2d 161, 126 USPQ 383; *In re Watanabe*, 50 CCPA 1175, 315 F.2d 924, 137 USPQ 350. It is neither possible nor desirable to recite every possible permutation of an invention within a patent. That freeze-drying is only recited in one example does not mean that Boyce does not anticipate the invention as claimed. On the contrary, Boyce discloses many features that "the bone-derived implant of *this invention* can optionally possess" (see, e.g. col. 4, lines 22-23 and 53, emphasis added). In example 1, still referring to "this invention," Boyce continues to disclose that the bone, which has already been shown to explicitly include a liquid organic agent such as a polyethylene glycol, can be freeze-dried (see col. 6, lines 45-46 and 50-52). Thus, "this invention," i.e. the invention of Boyce, includes within its scope bone that is contacted with a liquid organic agent and freeze-dried.

In response to applicant's argument that Boyce fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e.,

Application/Control Number: 09/940,545

Art Unit: 3732

Page 5

unaltered collagen fiber orientation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, this does not in any way prove that Boyce does not have liquid organic material throughout the entire freeze-drying process, since Boyce does not even discuss fiber orientation. However, Boyce does explicitly say that the various substances, including the liquid organic material, "can be incorporated into the bone-derived implant of *this invention* or any of its constituent layers during *any* stage of the assembly of the implant," which necessarily includes the stage wherein the bone is freeze-dried (col. 5, lines 24-28).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Page 6

Application/Control Number: 09/940,545
Art Unit: 3732

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

O2

D. Comstock 07 March 2005

EDUARDO C. ROBERT PRIMARY EXAMINER

EXHIBIT B

08/14/2005 16:05 FAX 2024527074

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Date

August 10, 2005

Phone

Fax

To

Mail Stop Appeal

703-308-4357

571-273-8300

From

W. Jackson Matney, Jr.

202-835-1678

262-452-7074

Client/Matter No.

95176562-005004

Applicant: Lloyd Wolfinburger, Jr.

Serial No.: 09/940,545 Filed: August 29, 2001

Title: Plasticized Bone and Soft Tissue Grafts ...

Pages (w/cover)

Please see attached Certificate of Transmission under 37 CFR 1.8, Notice of Appeal from the Examiner to the Board of Patent Appeals and Interferences, and Petition for Extension of Time Uniter 37 CFR 1.136(a) for filing with the United States Patent and Trademark office today.

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2002/004

PTO/SB/97 (08-03)

Approved for use through 97/3 (2006, OM) 00(4-19(4))

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For: Application Serial No. 09/940,545

- 1) Notice of Appeal from the Examiner to the Board of Patent Appeals and Interferences
- 2) Petition for Extention of Time Under 37 CFR 1.136(a)

The extension of unformation is required by 37 CFR 1.0. The information is required to obtain or return is benealed by the public which is to fin form by the USPTO in paccoss) an application. Confidence by a givenned by 35 U S C. 122 and 37 CFR 1.14. This collection is collection to take 1.2 question by complete, including galliants, preparely, and schooling the complete approaches form to the USPTO. Through which provide upon the individual case. Any commands on the unique to complete the form and/or suggestions for heliuming has benefit, should be said in the Chief information Offices, U.S. Potent and Hadronack Office, U.S. Department of Sommerce, P.O. Box 1450, Alexandria, VA 2213-1450, (Control of School of Schoo

If you need assistance in completing the form, call 1-300-PTO-9159 and select option 2

PAGE 24 ' REVD AT 9/14/2005 4:04:10 PM [Eastern Daylight Time] ' SVR:USPTO-EFXRF-6:00 ' DXIS-22/38300 ' CSÉD:20245/27074 ' DURATION (min-ss):01-24

EXHIBIT Ċ



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Parest and Tradestark Office
Adverse COMMISSIONER FOR PATENTS
P.D. Ban MD
Alexandra, Verghia 72013-1410

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. CONFIRMATION	
09/940,545	08/29/2001	Lloyd Wolfmbarger JR.	587/2.000004 5273	
. 7:	90 09/21/2005	•	EXAMINER	
	D GILCHRIST		COMSTOCK, DAVID C ART UNIT PAPER NUMBER	
1445 ROSS AVEN DALLAS, TX 75	VENUE, SUITE 3200			
DALLAS, IA	73202		3732	
			DATE MAILED: 09/21/200	5

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

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MAY **0 4** 2006

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	Application No.	: T	Applicant(s)	
		. 1	WOLFINBARGE	RETAL.
Notice of Abandonment	09/940,545 Examiner		Art Unit	
*****		,	n700	
	David Comstock		3732	ldress-
- The MAILING DATE of this communication ap	pears on the cover sheet v	aigu ruð Co	hi gahninging an	
This application is abandoned in view of:		:		
 Applicant's failure to timely file a proper reply to the Offical (a) A reply was received on (with a Certificate of period for reply (including a total extension of time of the control of the control of time of the control of the	month(s)) which ex	pirèdian _	 , which is after the 	
(b) A proposed reply was received on but it does	s not constitute a proper rep	Magnata National	rendment which d	aces the
(A proper reply under 37 CFR 1.113 to a final rejecti application in condition for allowance; (2) a timely fill Conlinued Examination (RCE) in compliance with 3	ed Notice of Appeal (with ap 7 CFR 1.114).	pearree), (or (3) a unlesy med	Mednest to
(c) A reply was received onbut it does not const final rejection. See 37 CFR 1.85(a) and 1.111. (Se	titute a proper reply, or a bor e explanation in box 7 below	na fide atte ').	mpt at a proper re	ply, to the non-
(d) No reply has been received.				
Applicant's failure to timely pay the required issue fee a from the mailing date of the Notice of Allowance (PTOL)	.•B5).		I .	
 (a) The issue fee and publication fee, if applicable, we have a state of the expiration of the statutory Allowance (PTOL-85). 	vas received on (with period for payment of the is	ı ei Certific sue fee (a	ate of Mailing or 1 nd publication fee)	ransmission dated set in the Notice of
(b) The submitted fee of \$ is insufficient. A balan	nce of \$is due.			
The issue fee required by 37 CFR 1.18 is \$		ired by 37	CFR 1.18(d), is \$	
(c) The issue fee and publication fee, if applicable, has	not been received.	-		
 Applicant's failure to timely file corrected drawings as re Allowability (PTO-37). 			į.	
 (a) Proposed corrected drawings were received on after the expiration of the period for reply. 	(with a Certificate of Mai	ling or Tra	nsmission dated _), which is
(b) ☐ No corrected drawings have been received.	•			
4. The letter of express abandonment which is signed by the applicants.	(he attorney or agent of reco	ord, the as	signee of the entin	e interest, or all of
 The letter of express abandonment which is signed by 1.34(a)) upon the filing of a continuing application. 	an attorney or agent (acting	in a repre	sentative capacity	under 37 CFR
The decision by the Board of Patent Appeals and Inter- of the decision has expired and there are no allowed or		and becau	ise the period for s	eeking court review
7. The reason(s) below:				
Examiner contacted applicant's representative of prosecuting the application and that no response	Frecord, Jenkins & Gilchri has been segt EDUARDO C. ROBERT FORMARY EXAMINER	ist, and w	as informed that	they are not
Peditions to revive under 37 CFR 1.137(a) or (b), or requests to will minimize any negative effects on patent term.	hdraw the holding of abandonm	ent under 3	 7 CFR 1.181, should 	be promptly filed to
U.S. Paters and Tradement Office	ice of Abandonment		Part	of Paper No. 091605

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